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- (b) A request for a hearing will be granted if the material submitted shows the following:
- (1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.
- (2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.
- (3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.
- (4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal. A hearing will be granted upon proper objection and request when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient.
- (5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.
- (6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.
- (c) In making the determination in paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in §10.30(h) or in

- other applicable regulations, e.g., §§ 314.200, 514.200, and 601.7(a).
- (d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, the Commissioner may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed order to demonstrate that the submission justifies a hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 399, Jan. 5, 1999]

§12.26 Modification or revocation of regulation or order.

If the Commissioner determines upon review of an objection or request for hearing that the regulation or order should be modified or revoked, the Commissioner will promptly take such action by notice in the FEDERAL REG-ISTER. Further objections to or requests for hearing on the modification or revocation may be submitted under §§12.20 through 12.22 but no further issue may be taken with other provisions in the regulation or order. Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in due course.

§ 12.28 Denial of hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published.

- (a) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by \$12.35, and will specify the objections and requests for hearing that have been granted and denied.
- (1) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.
- (2) The notice will confirm or modify or stay the effective date of the regulation or order involved.